**AMENDMENT OF OTHER TRANSACTION AGREEMENT (OTA)**

OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)

BETWEEN

**JANSSEN RESEARCH & DEVELOPMENT LLC**
920 ROUTE 202
RARITAN, NJ 08869, USA

AND

**THE UNITED STATES OF AMERICA**
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY**
O'NEILL HOUSE OFFICE BUILDING
WASHINGTON, DC 20515

CONCERNING

**INFLUENZA PORTFOLIO AND OTHER EMERGING PATHOGENS DEVELOPMENT CANDIDATES**

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Amendment No. 0006
Effective Date of Amendment: Upon Last Signature in Section III

Other Transaction Agreement No. HHSO100201700018C
Effective Date of Agreement: August 15, 2017

Except as provided in this Amendment, all terms and conditions of the Agreement, as heretofore changed, remain unchanged and in full force and effect.

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I. AMENDMENT PURPOSE

By the Parties' mutual agreement and within the existing Agreement's general scope, this Amendment No. 0006 bilaterally:

i. adds an additional asset to develop a vaccine in response to the current novel coronavirus ("2019-nCoV") outbreak,

ii. incorporates a realigned budget structure around (b) (4) and the 2019-nCoV asset. (b) (4) [redacted]

iii. updates the Statement of Work (Exhibit-A) to reflect 2019-nCoV work packages. The 2019-nCoV asset work packages 6.1 – 6.7 (CLINs 0001- 0007) as described on the Exhibit-A, Statement of Work are considered added and funded non-severable independent work packages as of the date of this amendment. Work Package 6.7 is an option to be exercised at a future date based on (i) JOC recommendation, (ii) availability of funding and (iii) a signed amendment between the Parties,

iv. modifies the PMO steering committee and USG agreement team to add the respective Technical Leads for this 2019-nCoV Vaccine development, and

v. adds the essential considerations.

II. AMENDMENTS TO AGREEMENT

A. Incorporate new budget and workplan structure to reflect the new 2019-nCoV asset and redirected (b) (4) [redacted].

1) Pursuant to Agreement Article VI(C), the budget allocation summary of assets is hereby replaced to incorporate the following.

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| Summary | Invoiced 8/15/2017 Through 12/31/2018 | 1/1/2019 Through 12/31/2019 | 1/1/2020 Through 12/31/2020 | 1/1/2021 Through 12/31/2021 | 1/1/2022 Through 12/31/2022 | Total |
|---|---|---|---|---|---|---|
| (b) (4) (BARDA:Janssen) Cost Share | | | | | | |
| (b) (4) | | | | | | |
| (b) (4) (BARDA:Janssen) Cost Share | | | | | | |
| (b) (4) | | | | | | |

| Total | (b) (4) |
|---|---|
| BARDA funding | |
| Janssen funding | |

(b) (4)

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(b) (4)

| 2019-nCoV Vaccines | |
|---|---|
| WP 6.1 | CLIN 1: Discovery including preMVS |
| WP 6.2 | CLIN2: pre-clinical immunology and effica |
| WP 6.3 | CLIN3: CMC development |
| WP 6.4 | CLIN4: Clinical development |
| WP 6.5 | CLIN5: GLP Tox study |
| WP 6.6 | CLIN6: GMP manufacturing |
| WP 6.7 | OPTION-CLIN7: Ph1 clinical trial |
| TOTAL | |

(b) (4)

2) Exhibit B budget allocation summary provide details for the budget restructuring are incorporated and attached to this Amendment 0006. (b) (4) [redacted].

B. Updated the Statement of Work

1) The Statement of Work shall be replaced to reflect the new asset structure. The updated SOW for incorporation in the OTA is included in Exhibit A.

C. Update of Recipient's Key Personnel and the Government's personnel working under the Agreement

1) Article IV *Management of the Project* Section A (3) *Organizational Chart* is deleted and replaced with the following:

(b)(4), (b) (6) [redacted]

D. Due to the urgency presented by the current threat and to assure Janssen is able to expeditiously and compliantly execute the SOW, BARDA/ASPR agree to exercise their statutory authority to the maximum extent practical to negotiate additional terms and waivers of existing OTA terms, laws and regulations, as listed below or as may arise during performance of this additional work, to enable Janssen, as a nontraditional government contractor, to execute performance consistent with its commercial practices. These provisions represent the underlying assumptions upon which the estimated cost and schedule have been developed.

1. Adherence to commercial practices when engaging subcontractors, including relief from flow down provisions that otherwise may apply.

(b) (4)

[redacted]

3. As it is not known at this time what the final composition and manufacturing technology of the vaccine shall be, any IP (patent or technical data)rights (including third party rights) that are needed to fully launch/deploy the final vaccine will be subject to pre-existing obligations and as well as negotiation by the appropriate parties at that time. The final negotiated rights shall, at a minimum, be consistent with the USG's IP rights specified under Articles IX and X of the OTA.

4. Due to the emerging nature of this threat, it is not possible to know the full extent of the threat, its impact, or the necessary resources required to control the virus. To the extent other parties, such as other agencies, international organizations, governments or NGOs, seek Janssen's participation in the effort to develop solutions to counter the threat of the coronavirus, BARDA will not place undue restrictions on Janssen's ability to collaborate with these other parties, including receipt of funding, use of Janssen's technology, or any other support or collaboration that Janssen determines is needed. BARDA's intellectual property rights will be consistent with the terms within Articles IX and X of the OTA.

5. Reporting Requirements of the above referenced OTAs will include only those requirements necessary to maintain sufficient updating during this dramatically accelerated vaccine development program.

6. To expedite the negotiation of 3rd party agreements and consistent with BARDA's flexibilities, the Government's right to audit financial records be limited to the records of those Parties that are relevant for performance of this Agreement for a period not to exceed three years after the expiration of the term of this Agreement.

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III. SIGNATURES

Acknowledged, accepted, and agreed for

JANSSEN RESEARCH & DEVELOPMENT, LLC

(b) (6)

DATE: 2/11/20

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF THE ASSISTANT SECRETARY FOR
PREPAREDNESS & RESPONSE

(b) (6)

NAME: GEORGE J. KEANE, JR.
ITS: OTAO
DATE: 2/11/2020

## ATTACHMENT 1: TASK DESCRIPTION DOCUMENT (SOW)

Overall Objectives and Scope

Seasonal and pandemic influenza remains one of the most important public health threats despite current vaccine and therapeutic options. The Consortium is developing a broad portfolio of innovative and novel countermeasures against influenza and other emerging infectious diseases comprising small molecules, biologics and vaccines. The portfolio employs (b) ( modes of action complementary to current Standard of Care treatments to develop single or combination therapies that have the potential to increase therapeutic benefit and preclude the rapid emergence of drug resistance. The (b) (4) aims to (b) (4) the influenza vaccine field by providing broad protection for both seasonal and pandemic influenza.

Specifically, this Agreement includes: an influenza (b) (4) that is now ready for (b) (4) (b) (4); a (b) (4) influenza A or B viruses; (b) (4) (b) (4); and (b) (4)

In addition, Recipient may propose to augment the portfolio by replacing molecules listed in this SOW with backup molecules from their ongoing research programs. With support from the JOC, the Consortium may also consider in-licensing drug or vaccine candidates to supplement the Program's portfolio of emerging infectious disease medical countermeasures in the Field. Recipient may also add Consortium Members as may be appropriate or complimentary to the performance and goals of this Agreement.

(b) (4)

(b) (4)

(b) (4)

6 Novel Coronavirus ("2019-nCoV") Vaccine

**6.1 Antigen design, manufacturability testing and preMVS manufacturing**

*Activities*

- Several designs based on the 2019-nCoV spike sequence will be made and ordered at multiple CROs
- Ad26 research batches encoding the different spike variants will be produced
- A small-scale manufacturability test will be done to determine platform fit of the different Ad26-vectors

(b) (4)

- The PreMVS will be released based on the following assays:

(b) (4)

- Several critical reagents such as expression plasmids, soluble proteins, peptide pools and detection antibodies will be generated or ordered

*Milestones*

- Selection of antigen for start of preMVS manufacturing
- Transfer of preMVS to development organization
- Release of preMVS (Triggers CLIN 0007)

*Deliverables*

- (b) (4)
- PreMVS CoA

- PreMVS manufacturing report

  *Go/No go decisions*

- Outcome (b) (4) triggers go for preMVS manufacturing and start of CMC method development and GMP manufacturing preparations
- Selection of antigen for start of preMVS manufacturing **(Triggers CLIN 0006)**

### 6.2 pre-clinical immunology and protective efficacy

*Activities*

- Mice, (b) (4) and non-human primates (NHP) will be immunized with DNA constructs of candidate vaccine inserts to set up immunogenicity assays and to determine immunogenicity
- Ad26-based candidate vaccines will be tested for immunogenicity (b) (4) mouse (b) (4), syrian hamster, (b) (4) and NHP
- Viral challenge models will be assessed in mice, Syrian hamster, (b) (4) and NHP (b) (4) (b) (4)

*Milestones*

- Initial PoC based on immunogenicity of DNA vaccine constructs
- (b) (4) PoC based on protective efficacy of Ad26-based vaccine candidate

*Deliverables*

(b) (4)

- Study reports of in vivo studies

  *Go/No go decisions*

- Proof of immunogenicity triggers go for preMVS manufacturing

(b) (4)

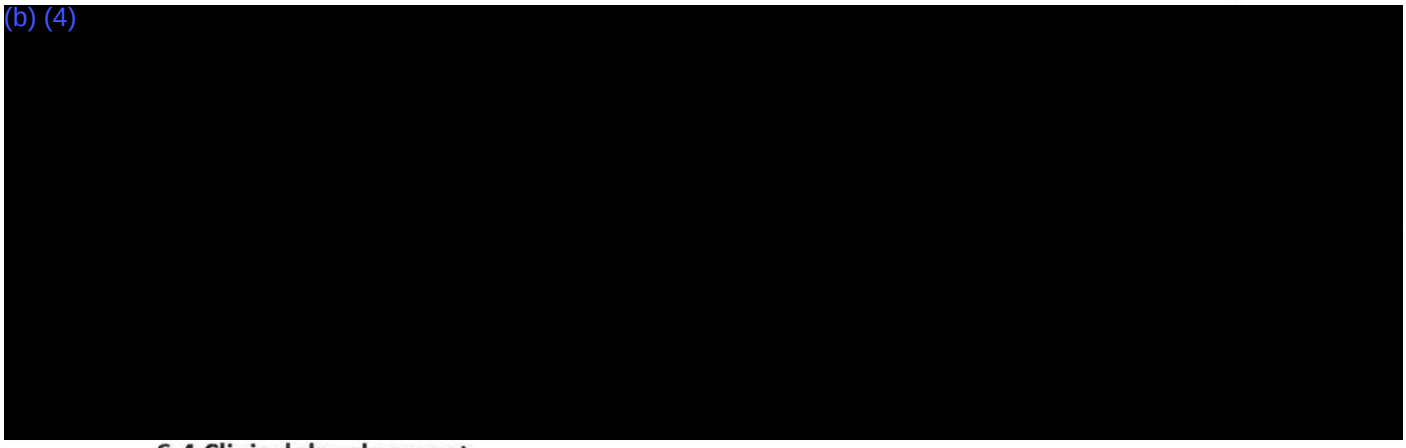
### 6.3 CMC development

*Activities*

(b) (4)

- (b) (4) method development will occur to make insert specific assays fit for purpose.

(b) (4)



**6.4 Clinical development**

*Activities*

- Setup of immunological assays
  - ELISA, VNA, ICS and ELISpot
- Writing of protocol elements document (PED)
- Protocol writing
- Writing and submission of preIND document
- Writing and submission of IND documents
- Contracting with CRO clinical site

*Milestones*

- PreIND meeting
- IND open

*Deliverables*

- Development reports assays
- PED
- Protocol
- preIND briefing book
- preIND minutes
- IND

*Go/No go decisions*

- preIND submission triggers start clinical trial **(CLIN 0007)**

### 6.5 GLP Toxicology

*Activities*

- A GLP Toxicity study will be performed in the rabbit.

(b) (4) [redacted]

### 6.6 GMP manufacturing

*Activities*

- Master Virus Seed manufacturing and release
- Drug substance manufacturing at appropriate scale (b) (4) [redacted]
- Drug product manufacturing (b) (4) [redacted] and release
- DS and DP stability analysis

(b) (4) [redacted]

(b) (4)

[redacted]

### 6.7 Ph1 clinical trial – OPTION Work Package

*Activities*

- Randomized, placebo-controlled, double blind study in healthy adult volunteers
- Primary objective will be assessment of safety and reactogenicity. Secondary and exploratory endpoints will evaluate vaccine-induced immunogenicity.
- Two dose levels (high dose and low dose) given intramuscularly will be evaluated as a single immunization or a two-immunization regimen and compared to placebo
- Serum and PBMC will be collected at day of immunizations, 7, 14 and 28 days after each immunization. Follow up for durability will be at 6 months and after one year.
- Group sizes will be 20+5 subjects per group for a total of 125 subjects in the study. 25 of these subjects (5 per group) will be enrolled at BIDMC to allow additional exploratory immunogenicity analysis, including potentially passive transfer studies if such model can be developed.

*Milestones*

- Primary analysis top line results
- Final analysis top line results

*Deliverables*

- TLR reports
- Clinical study report

*Go/No go decisions*

- Outcome of primary safety and immunogenicity analysis will trigger further clinical development beyond the scope of the current SoW.

# 7 Project Management

(b) (4) [redacted]

## 7.1 Joint Oversight Committee

The Joint Oversight Committee (JOC) is the larger decision-making body that provides guidance, direction and control to the projects to ensure execution of the projects according to the SOW. The JOC will discuss and approve any changes to the SOW. To that extent, the JOC will meet at critical decision points in the program, but no less than two times per year, preferably face to face or alternatively by WebEx or telephone conference. Ad hoc meetings will be organized when urgent matters arise. The JOC will consist of voting and non-voting members from BARDA and Janssen. Additional, non-voting members can be assigned or invited on an ad hoc basis. Decisions to reprioritize specific projects and resources as the need arises will be taken by consensus. In case such a decision cannot be reached in the JOC, the decision will be escalated to one BARDA and one Janssen senior management member identified at the start of the project.

## 7.2 PMO Steering Committee

The PMO (Program Management Organization) steering committee has dual responsibilities. One area of responsibility is the communication and coordination with BARDA regarding day to day management and execution of the project e.g. organizing meetings on a regular agreed basis. In addition, the PMO Steering Committee will coordinate all SOW activities and provide the technical and administrative infrastructure to ensure efficient planning, initiation, implementation, direction, management and completion of all tasks. This will be coordinated by the Project Manager Leader (PML). The Steering Committee will assess progress and where needed will work out strategic changes to be decided upon by the JOC. The Steering Committee consists of a group of dedicated and specialized Project Management experts, key personnel and additional specific expertise for the functions that are required for executing the specific work scope for each proposed asset area.

## 7.3 Asset Project Management

These WPs include the Program Management activities associated with each of the assets. Each asset will have an Asset Project Management Leader (Asset PML) who will oversee their specific Project Management requirements. This includes conducting frequent and regular Project Management Team (PMT) meetings to ensure the accurate developing and tracking of the budget, timeline and resource plan. The Project Management team of each asset will also include relevant functional Project Managers and a Finance Representative. Each asset will also have an Asset Technical Lead who will oversee their specific Technical requirements. This includes conducting frequent and regular Compound Development Team (CDT) meetings to define the overall development strategy. The CDT of each asset will include Technical Lead, Preclinical Leader, Clinical Leader, the CMC Leader and, the Regulatory Leader. Additional expertise

required for executing asset-specific work possibly including subcontractors may be added as part of PMT and CDT.

M00006 Exhibit B – Budget Allocation Summary

(b) (4)

[redacted]

| 2019-nCoV Vaccines | |
|---|---|
| WP 6.1 | CLIN 1: Discovery including preMVS |
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| TOTAL | |

(b) (4)

[redacted]